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Process and system for the monitoring of the material flow during the preparation for sterile goods

A process for the monitoring of the material flow during the preparation for sterile goods includes the following steps: the goods to be sterilized are packaged into a sterilization container (14). The data for the thus created unit to be sterilized (12) will be collected and stored onto a data carrier (32) that can be attached to the unit to be sterilized (12). The unit to be sterilized (12) will be sterilized in a sterilizer, and the data that characterizes the sterilization will be collected and recorded. The data that characterizes the unit to be (sterilized 12) will be entered into a data processing unit (46) that is connected to the sterilizer. A suitable sterilization process will be selected depending on the data that characterizes the unit to be sterilized (12). The data characterizing the unit to be sterilized (12) and the data characterizing the sterilization process will be stored together.

The invention is concerned with a process meant for the monitoring of the material flow during the preparation for sterile goods according to the inclusive meaning of claim 1, as well as with the execution of such a process according to the inclusive meaning of claim 12.

Sterilized goods are utilized in hospitals. "Sterilized goods" is the summarizing term for aids to be used for medical applications, and for which said aids are packaged and have to undergo a sterilization process that is monitored for its efficacy. In the following, a packaged unit of sterilized goods will be called a "sterilized unit".

Process conditions during the sterilization process that are inadequate jeopardize the hygienic safety of the sterile goods, and thus the life and health of the patients treated herewith.

The nursing personnel in hospitals, respectively, the hospital administration has the duty to responsibly consider the legal rights of the patient which is the "life and the health" of said patient. For the case that an endangered patient wants to hold a hospital or the nursing personnel responsible for any harm received by said patient, the proving of such inflicted harm will be reversed, which means the defendants needs to prove, among other facts, that sterile goods were used for the procedure that were in a hygienically appropriate condition. Thus the necessity exists for the hospital administration and for the hospital personnel to prove the appropriate hygienic preparation of the sterile goods without any doubt.

Indications of data that should be used to identify such sterile goods can be found in DIN 58953, Part 9:

Sterilization containers have to be marked in such a way that it is clearly observable that their content was subjected to a sterilization process. For this purpose the sterilization containers have to be equipped with a treatment indicator. It has to be identifiable whether the sterilization container has been opened prior to the utilization of the sterilized goods. Furthermore, it is required that the sterilization containers will be marked

a) with the names of the materials they contain
b) with the sterilization date (day, month, year)
c) with the name and the signature of the person who packed the container

All information has to be clearly readable and it has to be possible to identify it with a single glance. Furthermore it is required to display the expiration date that is calculated based on the possible storage duration.

According to the present state of the art, this identification process happens as follows:

Utilized as a process indicator is a paper label that has been printed by means of an indicator ink and which is inserted into the package or which is attached to the outside of said package.

For indicating whether the package has been opened the sterilization container will either be equipped with a seal or the container itself has been sealed, and upon opening the container this seal or sealing system will be broken.

The contents of the sterilization container will be identified by means of engraved labels that have been applied to the outside of said containers. For the case that paper or fabric packaging materials will be used, it is common to apply a strip of adhesive tape to said packages and mark said strips by means of a felt tip pen.

For example, the sterilization date will be written by hand onto a paper label that will be applied to the outside of the unit to be sterilized. Commonly this will be the same label that has the indicator ink applied to it. It is also possible to print the date onto a label by means of a labeling gun of the kind that is used for marking the prices on items to be sold in stores that sell merchandise to the public.

The signature of the person that packages the items is commonly placed onto the paper that also contains the sterilization date by means of signing said label. It is also possible that metal coins or indicators are utilized that can be used several times over again and that bear the identification number of the person responsible for creating the pack.

In order to presently create proof of the proper sterilization processing of the pack, the physical parametric data of the sterilization process will be either recorded with the support of digital recording equipment (data printer for the measurement data), or it will be recorded by means of analogous recording equipment. Herewith, the recorded data includes the identification of the selected sterilization process, the sterilization date, if required, the lot number, and as process data it includes the processing time, the temperatures and the pressures.

With the most modern systems that are utilized presently, packaging labels will be supplied by a printer at the sterilizer that contains the data for the "sterilization date", "identification number of the sterilizer", and "lot number" of the sterilized pack. These labels will be attached to the units to be sterilized. It is possible, if so desired, to transfer this data at a later time into the treatment protocol. It is also possible to register an expiration date on such a label. However, the identical expiration time duration will be used herewith for the calculation of the expiration date. Herewith it is not possible to take consideration of the kind of packaging material and the storage conditions. This is because of the fact that the relevant data processing unit has no input information on the sterile units to be processed. It is also not possible to

consider said labels as being individual identification markings of the units to be sterilized because of the fact that all units to be sterilized that are part of the same lot will bear the identical label.

During their utilization the sterilized units arrive at the site of their usage which is normally the operation room. Immediately prior to the usage, the packaging label will be checked again. A treatment protocol will be established for the purpose of documenting the treatment of the patient. The data of the sterilized unit that was either written down by hand, or that is contained on the label will be transferred by hand onto the treatment protocol. The treatment protocol will be retained for the entire duration time that could be required for proving the hygienic safety of the sterilized goods. In general, this will be for a time duration of 30 years.

For the case that a patient requests the proof of a safe hygienicly treated instrumentation from the hospital or the responsible personnel once the treatment has been finished, the treatment protocol will be retrieved, and the sterilizer lot number of the utilized sterilized unit will be obtained. By means of the physical process data that is recorded on the lot documentation that corresponds to the relevant lot number, the suitable sterilization process, and thus the appropriate hygienic quality of the devices of the relevant unit that has been sterilized, and that are utilized to support the treatment, shall be confirmed herewith. The above described method, and other known methods for documentation, are based on hand written records which are very labor intensive and unsafe concerning their creation. This is based on the possibility of any identification failures that might occur as well as due to the possibility that manipulations of the data are possible. Thus, any method to verify the hygienic quality herewith could be considered to be doubtfull concerning the accuracy of the information.

A major disadvantage of the presently common methods for the identification of goods lays in the fact that the data is spread across several data sheets and that it is thus possible to mix-up the allocation of such data. Furthermore, the creation of each of the data carriers is connected with additional workload and additional cost. The following is a listing of a number of possible failures:

Failure possibilities at the packaging area:

The package preparer forgets to insert the indicator (failure will only be detected during later use).

The package preparer forgets to identify the contents of the pack.

The package preparer forgets to note the sterilization date onto the paper label, or a wrong date is used.

The package preparer forgets to attach his/her signature to the pack.

Failure possibilities with the operation of the sterilization equipment:

The selection of the sterilization program has to happen by the operator of the equipment. Based on the loading of the unit the operator has to decide about the appropriate program for this specific load. Herewith, it is common that this selection decision exceeds the abilities of the operator. This applies specifically to those cases in which mixed loads are to be sterilized in the sterilization equipment. The personnel in the operation room, too, is very often not able to make any decision on the appropriate sterilization process, even if this personnel would recheck with the support of a possible notice that might be present, whether the appropriate sterilization program was applied to the pack.

For the case that labels will be supplied by the sterilization equipment at the end of the sterilization process, these labels have to applied to the treated sterilization units. Herewith it is possible again that failures may happen. Prior to the dispensing of the labels by the sterilization equipment, the number of the labels that need to be printed has to be entered into the sterilizer unit. In case of faulty input, it is possible that some sterilized units will either not receive any label or that surplus labels may be used for the wrong purposes. It is furthermore possible that the labels will receive a false allocation, which means, that lot X will be identified with the labels of lot Y.

Failure possibilities during storage:
Because of the fact that a characterization of the storage area is not common with the presently used documentation systems, the danger might exist that the goods might be stored under conditions that do not support the predetermined storage life times.

Failure possibilities during a required recall:
For the case that the responsible sterilization department identifies a functional defect with the sterilizer at a later time, and said department will thus be required to recall certain sterilized units that cannot be used, said department will not have any reliable information on the goods, the amount and the actual location of the relevant sterilized units, and this would only be different if additional hand written records would be available. Thus records can be created only in a very labor intensive manner, and failures cannot be excluded herewith. Because of the fact that it might not be possible with the goods that have not been retrieved neither to identify the failed sterilization process by means of the exterior condition of the pack nor by the indicator, it might be possible that such a unit might be used, and that thus the patient might be harmed.

Failure possibilities during transfer of the data:
The transfer of all or separate data from the sterilized unit onto the treatment protocol happens in a manual fashion that allows for the

possibility of transfer mistakes. Even for the case that certain data will be transferred by adhesively attaching a label into the treatment protocol that was printed out by the sterilizer prior to the transfer, it might be doubtful that the appropriate allocation of said label took place. This is because of the fact that the identical label could also have been obtained from a different sterilized unit that could have a totally different contend, but that would have been sterilized in the identical lot.

The scope of the invention is to identify the process that has been mentioned in the beginning of this document, and which allows for the seamless documentation of the preparation of sterile goods starting with the packaging process of such goods all the way to the usage of said goods. Because of said process it would be to proof the hygienic efficacy of the utilized sterile goods.

According to the invention this scope will be solved by means of a process of such kind as it is mentioned in the inclusive meaning of claim 1. Said scope will be solved in such a way that the data that characterizes the unit to be sterilized will be entered into a data processing unit that is connected with the sterilizer. A suitable sterilization process that depends on the data that characterizes the unit to be sterilized will be selected, and the data that characterizes the unit to be sterilized and also the sterilization process that is applied will be stored together. It would be preferable that the characteristic data of the sterilized unit and that of the sterilization process would be recorded together in a single protocol.

With the process that is executed according to the invention only a certain sterilization process that is identified by means of physical data can be possibly allocated clearly to an individually identified sterilized unit. Furthermore, it will be made sure that a unit to be sterilized will only be exposed to a sterilization process that is suitable for the relevant goods to be sterilized.

It is preferable herewith, that the data of the data carrier that is connected with the units to be sterilized, and the data of the protocols will be recorded in such a way that it can be read by means of machines. Thus it will be made sure that any manual data transfer will be eliminated. Herewith it will be possible to eliminate any failures caused by data transfer that also could occur during the manual data input into a data processing unit that would be conducted by an operator.

The individual identification of the sterile units will not exclude the combination of several units to be sterilized to create a lot prior to the sterilization process. This possibility allows the creation of a data carrier that is additional to the data carriers that are allocated to the separate single information, and this additional data carrier allows the creation of summarized information of the data that characterizes the various single units. For such a lot it is only required to enter the data of the summarizing label either manually or automatically. Thus one

avoids the work that is involved with entering or automatically transferring the information of each single label.

A lot protocol will be generated or a lot that is not required to necessarily consist of identical units to be sterilized. Every single sterilized unit will be identifiably listed on said lot protocol, for example, by means of allocating and recording consecutive numbers to each unit to be sterilized.

It would be of advantage if the data carriers that contain the data of the relevant sterilized units would be attached in a detachable manner with the sterilized units. For example, it could be possible that the data carriers would be created in the fashion of an adhesive label, and thus allow for their easy attachment to the units to be sterilized. A later removal of the sterilized units would be as easy in order to allow, for example, their adhesive attachment in the treatment protocols. Thus it will be avoided to transfer said data by means of hand writing and any possible failures associated with this process will also be eliminated.

If so desired it would be possible to utilize data carriers that contain two sections and the identical data sets would be recorded onto each of said two sections. One of said sections would remain with the end user, and it could be, for example, adhesively attached into the treatment protocol, while the other section remains at the sterilized unit. This would allow for the monitoring of reusable sterile goods like, for example, surgical instruments.

For the case that the data carrier for the unit to be sterilized and for the protocols will be created by means of electronic data processing equipment, it would be of advantage if the person who operates said equipment identifies him or herself by means of a personal identification system, and herewith it would be possible that the personal identification would be recorded on the data carrier, respectively, on the protocol. Herewith it would be possible to identify also a single person who would be responsible for the packaging, respectively, for the sterilization of a certain and identifiable sterilized unit.

It would be of advantage to again collect the data that is present on the data carrier prior to dispensing the processed sterilized unit to the end user, and to store this recollected data together with the data that characterizes the end user and the dispensing conditions. This would also allow to identify the path of an individual sterile unit all the way to the relevant end user. Furthermore, it would be possible to utilize this data for warehousing and inventory purposes. Finally it would be possible with the application of this method to monitor the expiration date of a relevant sterilized unit, and thus it would be possible to avoid dispensing said unit for the case that the expiration date has been exceeded already.

The process that is executed according to the invention would also allow the individual identification of each of the sterilized units without allowing any doubts about its identity, it would allow for the documentation of all pertinent data that are required for proving the efficacy of an adequate processing, storage and use according to the intended use of said sterilized units. Additionally, it also would allow for the monitoring of the sterilization process in dependence of the load, and also of the material flow of the sterilized goods.

Furthermore, the invention applies also to a system for the monitoring of the material flow during the preparation of goods to be sterilized, including the packaging station which is utilized for packaging the goods to be sterilized into a sterilization container, a sterilization station including a sterilizer used for the sterilization of the goods to be sterilized, and also of a storage area used for storing and dispensing of each of the sterile units that consist of the sterile goods and the container for the sterile goods. According to the invention, such a system is characterized in such a way that the packaging station is equipped with a data input installation that is used for registering the data that is characteristic data of the sterile goods units, and that it is also equipped with a data output installation that is used for recording the characteristic data of the sterile units onto a data carrier that can be attached to the unit to be sterilized, and that said system is also connected to a data processing unit that possesses a data input installation that is used for registering at least a certain amount of the data that characterizes the unit to be sterilized, and that it also possesses a data output installation that will be able to record the characteristic data of the sterilized unit, and also the data that is relevant to the sterilization process onto a second data carrier, and that the storage area possesses at least one data entry installation that is planned to be utilized for registering the data that has been recorded onto the first and/or second data carrier, and that it also is equipped with a data display installation that is to be utilized for the display of monitoring data. It can be considered to install independent data processing equipment in the warehousing and packaging areas. However, it would be preferable to connect the data entry and data output installations of the packaging station and of the warehouse with the data processing installation of the sterilization station. Thus, a data exchange can happen immediately between those different installations, and it would not be required to enter the data each time again upon changing the location of the sterile goods from one station to the next station.

It is preferred that the data entry installations possess means that allow the entry of personal identification data, thus allowing the operator of the packaging station, and/or of the sterilization station, and/or of the storage area to identify themselves by means of entering their personal identification. It would be possible, for example, that such an installation could be equipped with a card reader that would accept the input of an identification card.

It is preferred that the data entry installations possess data reading equipment to be used for data that is entered by means of a machine. This would be, for example, a reading installation for reading a bar code, or it also could be a magnetic tape reader. In this way it would be avoided that transfer failures would occur in the fashion as they do happen for the case of manual data input processes.

It is preferred that the data output installation of the packaging station would be equipped with a label printer to be used for printing adhesive labels. It would be of advantage if these labels consist of a carrier layer that possesses a first adhesive coating, and of a data carrier layer that adheres to the carrier layer by means of a second adhesive coating. Herewith it would be preferred if the adhesive strength of the second adhesive coating towards the carrier layer is lower than the adhesive strength of the first adhesive coating to an adhesive accepting surface of the sterile goods container. Because of this fact it would be possible at the packaging station to adhesively attach the adhesive labels to the sterile goods containers. The data carrier layer could now be removed by the end user , and they could be, for example, adhesively attached to the treatment protocol.

It is possible that the first data carrier could be equipped in the well known fashion with a treatment indicator that will react to the influences of the sterilization process. Furthermore, it is possible that the data carrier can be connected with the sterile goods container in such a way that it can only be removed from said container after the sterile goods container has been opened.

Further characteristics and advantages of the invention will result from the description that follows, and which explains the invention with the support of the attached drawing, and also with the support of an execution example. Displayed are in:

Figure 1	a schematic display of the packaging station, and of the documentation that takes place at the packaging station,
Figure 2	a schematic display of the sterilization station, and of the documentation that takes place at the sterilization station,
Figure 3	a schematic display of the warehouse are that is used for the sterile units, and of the processes that are connected to the dispensing of said units,
Figure 4	a schematic display of the documentation of the processes in the operating room that are concerned with the sterile goods.

Figure 1 displays a packaging station that is equipped with a packaging table 10, on which a unit to be sterilized is located that has the number 12 for its general

identification. Said unit consists of a sterile goods container 14 and the sterile goods that are located inside of it. Furthermore, a label printer 16 that is equipped with a keyboard 18 to be used for input purposes is located on top of the packaging table 10. Also located on top of said table is a bar-code reading pen 20, and a label output installation 22. Located at the right side of said packaging table 10 is a transport cart 24 on which a number of unit to be sterilized 12 will be collected to create a lot.

In general, the person who packs a unit to be sterilized 12 will also conduct the labeling procedure. Prior to the request for labels the person who is conducting the packaging process needs to identify him or her self by means of a personal identification code that allows the person to operate the label printer 16. In order to do this the person needs an identification card 26 that bears his or her personal identification code number in the form of a bar code that is printed onto said card. Said bar code will be read into the label printer 16 with the support of the reading pen 20. Alternatively, it is also possible that the person who conducts the packing process inputs his or her identification code number by means of the key board 18 that is connected to the label printer.

The person who conducts the packing process selects the labels that are specific for the goods by means of entering the article number of the relevant goods to be sterilized in to the label printer 16, or they will be entered by means of reading them into the said unit from an article number listing 30 which has the article numbers listed in the form of bar codes.

The label printer 16 dispenses one packaging label 32 each for each unit to be sterilized 12, and this label will be attached by adhesive means to the sterile goods container 14.

It is possible to enter into the label printer 16 that a whole row of packaging labels 32 belongs together as a series. In general, a series is the sum of all units to be sterilized 12 that together will create a lot load. The label printer 16 will automatically dispense a collective label 34 once it finishes dispensing all packaging labels 32. Said collective label 34 will be allocated to said series, and it could, for example, be attached to the lot cart 24. A collective label 34 always represents only one series of packaging labels 32 that represent the same kind of sterile goods. For the case that the lot load consists of a mixture of different kinds of goods, the relevant number of different collective labels 34 will be generated. However said collective labels 34 will still be long to one series. The collective labels that belong together will bear a consecutive numbering system, and the total number of the collective labels that belong to this series will be printed onto each of said collective labels.

The following data is contained in the data memory of the label printer 16:

The identification (code number) of the person of the packaging area that is allowed to operate it.

The specific data for the goods to be sterilized, and that are allocated to the relevant article number, such as article name, allowable expiration date, name and function of the end user of said article, and the number of the planned warehousing location for the relevant article.

The data that is not specific to the goods to be sterilized, such as identification number of the label printer, the name of the packaging department, and the packaging date.

Calculated data such as the expiration date that will be calculated from the packaging date plus the time duration that is the specific expiration time duration of the goods to be sterilized, consecutive number of each packaging label 32, starting and end number of the consecutive numbers of all packaging labels 32 that belong to a series of the same kind of goods, and also the number of the relevant collective label 34 as well as the total number of the collective labels 34 that belong to one series.

The consecutive number of the packaging label 32 is constructed from the identification number of the label printer and of a number that is increased continuously by the label printer. The consecutive number always has to contain the identification number of the label printer. This is because of the fact that several printers can operate in parallel to each other, and that it is not required that said printers are connected with each other in such a way that they would be able to exchange data with each other. Otherwise it could lead to the distribution of identical numbers if the printer would create a consecutive number and said number would not contain the identification number of the issuing label printer. Thus, an individual identification of each sterile unit would not be ensured any more.

The label printer 16 prints an article number onto the packaging label 32. Said article number includes the consecutive number of the unit to be sterilized and also the identification number of the label printer, as well as the expiration date and the warehousing location. Said printed information is coded in a bar code format. Printed in a normal readable alpha numerical way is the name of the packaging department, the name of the person which executed the packaging process, the name and the function of the end user, the article name, and the expiration date.

The label printer prints the article number onto the collective label, starting and end number of the consecutive numbers of all packaging labels 32 that belong to a series of the same kind of goods including the identification number of the relevant label printer, the number of the relevant collective label, and the total number of the collective labels that belong to one series, the expiration date,

and the warehousing location. Said printed information is coded in a bar code format. Furthermore, printed in a normal readable alpha numerical way is the article name and the name of the person who executed the packaging process.

Additionally it is possible, that an indicator color is printed at a suitable location onto the packaging labels 32. Said indicator print is not displayed herewith.

The packaging label 32 stays attached to the relevant sterile unit until said unit is utilized. The labels 32 have a double adhesive ability, and they are resistant against the conditions that influence them during the sterilization process.

The collective label 34 is also resistant against steam influences, and it remains with the relevant lot load until the data transfer by means of a bar code reading equipment at the sterilizer has been conducted in the way as it will be described later in this document. However, it is also possible to continue to use it as a data carrier all the way until the sterile goods will be dispensed, or even further on until it reaches the end user for the case that the lot load will not be split-up on its way to the end user.

Figure 2 displays a sterilization station with a sterilizer 36. Said sterilizer contains a sterilization chamber that can be closed with the support of a door 38. The transport cart 24 that contains the units to be sterilized 12 can be pushed into said sterilization chamber. Furthermore, the sterilizer 36 possesses a monitoring section 40 that is equipped with a data entry installation 42, with a data output installation 44, and with a data processing installation 46 that is connected to both of the other installations. This data processing installation 46 will be referred to in the future as being the documentation computer. The data entry installation 42 includes a keyboard that is not displayed herewith, and it also includes a bar code reading pen 48 It would be possible, of course, that the documentation computer 46 would be comprised of a separate installation that is connected with the monitoring unit 40 of the sterilizer 36 in order to conduct a data exchange process.

The documentation computer contains in its data memory at least the identification (code number) of the person that is allowed to operate the sterilizer, as well as the relevant article numbers of the different goods to be sterilized including the applicable sterilization programs for said goods that allow the appropriate processing of said goods, and it also contains the name of the sterilization department and the identification number of the sterilizer. The later is of importance for those cases in which several sterilizers are operated at the same time.

Entered into the documentation computer 46 will be the code number of the relevant operator. This operator needs to identify by means of a personal code number that allows him or her to operate the sterilizer 36. Herewith a bar coded

identification card is read by means of the bar code reading equipment 48. This process happens in a similar way as this is the case at the packaging station. Alternatively it is also possible that the operator enters the code number with the support of the keyboard of the data entry installation at the sterilizer 36.

Furthermore, data that is printed on the packaging labels 32, and/or on the collective labels 34 will be read into the documentation computer 46 by means of the bar code reading equipment 48. With the support of the data that is entered from the packaging labels, respectively, from the difference between the staring number and the end number of the consecutive numbers on the collective labels it is possible to calculate the number of sterile units per version of goods. Because of the fact that an allocation considering certain kinds of sterile goods in relation to certain sterilization programs has been programmed into the documentation computer 46, it will be possible for the documentation computer 46 to automatically select and start the appropriate sterilization program. For the case that different kinds of goods have been assembled to create one lot, and in case that there is no generally suitable sterilization program available for said lot, a relevant failure indication will be made by the documentation computer 46. Collected as being data during the sterilization process are the names of the selected serialization program, the sterilization date, the lot number, and the process data as well as the expiration dates, the temperatures, and the pressures.

The documentation computer 46 allocates the data that has been entered by means of the bar code reading equipment, or any data that has been entered into the documentation computer 46 by any other means to the data that is already present in its memory, and also to the data that is collected during the sterilization process. This data will be outputted at the end of the sterilization process in the form of a lot document 50.

Recorded on the lot document 50 are thus, beside the general data that characterizes the lot (name of program, lot number, date), and the process data (processing times, temperatures, pressures), the data that would be required to be the characteristic data for the case of a later recall of all those sterilized units that have been treated with this relevant process. This data would include the article numbers, the amount of each kind of goods (article), as well as the consecutive number, the expiration date, and the warehouse location number of each of the sterilized units.

The personnel that is responsible for the sterilization has to check the lot document 50 to ensure its accuracy concerning the process data, and said personnel has to sign the lot document 50, or verify said document with a different unmistakable means prior to the utilization of the sterile units. For the case that the operator(s) identifies abnormalities the utilization of the relative sterilized units have to be inhibited. Based on the data that is present on the lot

document 50, the operator will be able to identify the number, the warehouse location, and the consecutive number of each of the sterilized units. Thus the operator will be able to locate these units again and retrieve them from the identified location.

The lot document 50 will be retained for the entire time duration that could be required to prove the hygienic efficacy . In general, this time duration will amount to thirty years.

Once the sterilization process has been terminated successfully, the sterilized units will be remove from the sterilizer and they will be stored in the relevant storage locations of a sterile goods storage area 52 (figure 3). Herewith the unloading of the goods will be considered by the documentation computer 46 as being the dispensing procedure of the sterile goods storage area 52. If so desired, herewith it is possible to identify the person(s) that unloaded the sterilizer equipment in the same manner as this has been described already for the personnel who are responsible for the packaging station and also for the personnel who are responsible for the sterilization station.

A data entry installation 54, and a data display installation 56 are planned to be located in the sterile goods storing area 52. Said installations are connected with the documentation computer 46 of the sterilization station for the purpose of any data exchange The data entry installation 54 is displayed as being bar code reading equipment that possesses a reading pen 58. It shall be understood that other means could be planned as being suitable for the data entry purposes, these other means could be, for example, a magnetic strip reader or a similar device.

Prior to leaving the sterile goods storage area 52 the packaging label 32 of each sterile unit will be read with the support of the reading pen 58. It would be of advantage to read the collective label 34, respectively, the collective labels 34 at the dispensing location for the sterile goods 60, for the case that not only single sterilized units but a complete lot that has not been broken down yet will be dispensed.

Based on the entered data, the documentation computer 46 monitors the expiration date immediately and compares it with the stored expiration date. For the case that the sterile units expiration date has expired a failure message will be displayed on the data display installation 56 of the dispensing location for the sterile goods 60. The dispensing of the relevant sterilized unit will then be inhibited.

Based on the fact that the characteristic data of each sterile unit 12 will be collected by the documentation computer 46 at their time of entrance into the sterile goods storage area 52, and also the time the said sterile unit 12 will be

dispensed, it will be possible to conduct a permanent inventory control of the warehouse content. The actual warehouse content at each given moment, and also the goods movements of the storage area can be printed out by means of the documentation computer 46.

For the case that several sterilizers 36 operated in parallel, it is required for the correct ware housing that all these sterilizers are connected to the documentation computer. This connection to the documentation computer 46 is for the purpose of the required data exchange. The documentation computer 46 registers the entry of each of the sterile units that are sterilized by each of the sterilizers that operate in parallel, and that come into the sterile goods storage area 52.

The largest amount of the sterile goods is utilized in the operating rooms. Such an operating room is indicated in figure 4 by means of an operating table 62. After opening of the sterile goods container 14, the packaging label 32 will be removed from the sterile goods container and it will be adhesively attached to the operation protocol 64. For the case that after the surgical treatment a patient requests from the hospital or from the responsible personnel the proof of the hygienic efficacy of the means that was used for his treatment and for the surgical procedure, the treatment protocol 64 will be retrieved. The consecutive number of the packaging label 32 that is applied to the sterile unit 12 that is used during the relevant treatment will be read.

The lot number document that bears the relevant number will be retrieved from the filled lot documents 50 of the one or several sterilizer(s) 36. By means of the evaluation of the physical data that are also recorded on this lot document 50 it is possible to prove that the goods were exposed to the appropriate and efficient sterilization process, and thus it is possible to prove the hygienic efficacy for the sterilization processing of the relevant treatment means that were obtained from the sterilized unit 12.

Because of this the back traceability for each sterilized unit is made possible all the way, from the usage with the patient back to the preparation of the unit. Thus the hospital is able to protect itself against unfounded regress one of the claims concerning failures during the preparation and processing of sterile goods.

During the execution of the process and system according to the invention it is still possible that failures could occur, however, the number of the possible failures will be reduced tremendously, and the identification of possible failures will be made easier. It could be possible, for example, that the person preparing the packs would forget to attach a label to said units to be sterilized. However, this failure will be detected already during the data entrance process at the sterilizer 36. It is not possible for the person preparing the packs to forget to

apply the treatment indicator, the content identification, information on the sterilization date, and his/her signature. This is not possible because of the fact that these identification means are either preprinted on the label or that they will be printed onto the label prior to dispensing said label.

At the sterilization station the operator could forget to enter single packaging labels. However, this failure could not happen for the case that collective labels would be used. This is because of the fact that the information on the total number of collective labels in a series will be recorded on each of the collective labels. The sterilization equipment indicates a failure for the case that not all of the packaging labels will be entered.

With the system that is executed according to the invention it is impossible that failures would occur, such as the selection of the wrong sterilization programs, wrong information on the number of the units to be sterilized, and the allocation of the appropriate labels to the relevant goods of a wrong lot.

Based on the fact that the appropriate storage location can be read on each of the packaging labels 32 it is rather impossible that a wrong storage location would be selected.

Because of the fact that each of the sterilized units is identified and recorded on the lot document 50 in an individual manner, and that also the further proceeding (warehousing location and end user) will be registered, it will be possible to locate each sterile unit 12. It is basically impossible to make any mistakes such as not recording the number of sterile units. Because of this it will be ensured during recall actions that all of the sterile units that need to be recalled will be covered.

The above description clearly displays that the system that is executed according to the invention practically allows for a secure and total continuous documentation of the sterile goods, starting from the preparation of said goods all the way through to the end user of said goods. It is also possible to ensure by means of appropriate measures that also the return of reusable goods that can be resterilized, such as, for example, clothing or surgical and medical instruments, will be documented, and thus it will be ensured that the circle of the sterile goods flow will be closed.

Patent One of the claims

1. Process for the monitoring of the material flow during the preparation of goods to be sterilized, with which said goods to be sterilized will be packaged into a sterile goods container (14), and with which for the thus created unit to be sterilized (12) identification data will be registered and stored on a data

carrier (32) that can be attached to the unit to be sterilized (12), and with which said unit to be sterilized (12) will be sterilized in a sterilizer (36), and with which the data that is characteristic for the sterilization process will be registered and recorded, **characterized** in such a way that the data that identifies the unit to be sterilized (12) will be entered into a data processing installation (46) that is connected with the sterilizer (36), and that, depending on the data that is characteristic for said unit to be sterilized (12) a suitable sterilization process will be selected, and that the data of the unit to be sterilized (12) and the data that identifies the sterilization process will be stored together.

2. Process according to claim 1, **characterized** in such a way that the data that identifies the unit to be sterilized (12) and the data that identifies the sterilization process will be recorded in a protocol (50).

3. Process according to one of the claims 1 or 2, **characterized** in such a way that the data that that is recorded on the data carriers (32, 34) that can be attached to the unit to be sterilized (12), and/or the protocols will be recorded in a form which allows it to be read by machines.

4. Process according to one of the claims 1 through 3, **characterized** in such a way that units to be sterilized (12) will be collected prior to the sterilization process to create a lot of sterile goods, for which a collective data carrier (34) will be created in addition to the data carrier (32) that is allocated to the single units to be sterilized (12), and that said collective data carrier (34) contains the characteristic data of the units (12).

5. Process according to claim 4, **characterized** in such a way that a lot protocol will be generated for the sterile goods lot that includes several units to be sterilized (12) that will be exposed to the identical sterilization process.

6. Process according to one of the claims 1 through 5, **characterized** in such a way that the data carriers (32) can be connected in a detachable way with the units to be sterilized (12).

7. Process according to claim 6, **characterized** in such a way that adhesive labels will be utilized as the data carriers (32).

8. Process according to one of the claims 6 or 7, **characterized** in such a way that the relevant data carrier contains 2 sections onto which the identical sets of data will be recorded, and with which one of said sections will be removed away from the sterilized unit by the end user of the sterile goods while the other of said sections remains on the sterile unit that will be returned by the end user for the purpose of exposing it to a new sterilization process.

9. Process according to one of the claims 1 through 8, **characterized** in such a way that the data carriers (32) for the units to be sterilized (12), and also for the protocols (50) will be produced by means of electronic data processing equipment (16; 46, 44), and that the operator of the relevant equipment has to identify him or her self with the support of entering a personal identification

code, and that said personal identification will be recorded onto the data carrier (32), respectively, onto the protocol (34).

10. Process according to one of the claims 1 through 9, **characterized** in such a way that the data on the data carrier (32) will be recorded again upon dispensing a sterilized unit (12) to an end user, and that said data will be stored together with that data that is characteristic for the end user and also for the conditions for dispensing said unit.

11. Process according to claim 10, **characterized** in such a way that the data that has been stored upon dispensing a sterilized unit (12) to an end user will be transferred to the data processing installation (46) of the sterilizer (36) , and that said data will be checked there with the support of the data that has been stored there for the relevant sterilized unit (12), and that a release information that depends on the outcome of said checking procedure will be transmitted to the dispensing location, and that at said location an inventory control will be executed.

12. System for monitoring the material flow during the preparation of sterile goods, including a packaging station for the purpose of packaging the goods to be sterilized into a sterile goods container (14), a sterilization station that is equipped with a sterilizer (36) to be used for the purpose of sterilizing the goods to be sterilized, and a warehouse or storage area (52) for storing and dispensing the sterile unit (12) that consists of the sterile goods and of the sterile goods container (14), **characterized** in such a way that the packaging station is equipped with a data entrance installation (10, 20) for collecting the data that characterized the sterile unit (12), and that said packaging station is also equipped with a data output installation to be used for recording the data that characterizes the sterile unit onto a data carrier (32), and that said data carrier can be attached to the sterile unit (12), and that the sterilizer (36) is connected with a data processing installation (46) that is equipped with a data entrance installation (42, 48) to be used for recording at least a certain amount of the data that characterized the sterile unit (12), and that said sterilizer is also equipped with a data output installation (44) to be used for recording the data that characterizes the sterile unit and the sterilization process onto a second data carrier (50), and that the storage location (52) is also equipped with at least one data output installation (54, 58) to be used for collecting the data that has been recorded onto the first and/or the second data carrier, and that it is also equipped with a data display installation (56) that is used for the purpose of displaying monitoring data.

13. System according to claim 12, **characterized** in such a way that the data entrance and output installation (16) of the packaging station, and/or the data entrance and data display installation (54, 58, 56) of the storage location (52) is connected with the data processing installation (46) of the sterilization station for the purpose of exchanging data.

14. System according to one of the claims 12 or 13, **characterized** in such a way that the data entrance installations (18; 42; 54) are equipped with means to allow for entering personal identification data.

15. System according to one of the claims 12 through 14, **characterized** in such a way that the data entrance installations are each equipped with a data reading installation (20; 48; 58) to be used with data that can be read by machines.

16. System according to one of the claims 12 through 15, **characterized** in such a way that the data output installation (22) of the packaging station consists of a label printer.

17. System according to claim 16, **characterized** in such a way that the first data carriers (32) consist of adhesive labels that contain a carrier layer that is equipped with a first adhesive coating, and said adhesive labels contain a data carrier layer that adheres by means of a second adhesive coating in a detachable fashion to the carrier layer.

18. System according to claim 17, **characterized** in such a way that the adhesive force of the second adhesive coating to the carrier layer is lower than the adhesive force of the first adhesive coating to the sterile goods container (14).

Translated by:

Dietmar Schlei

736-2057

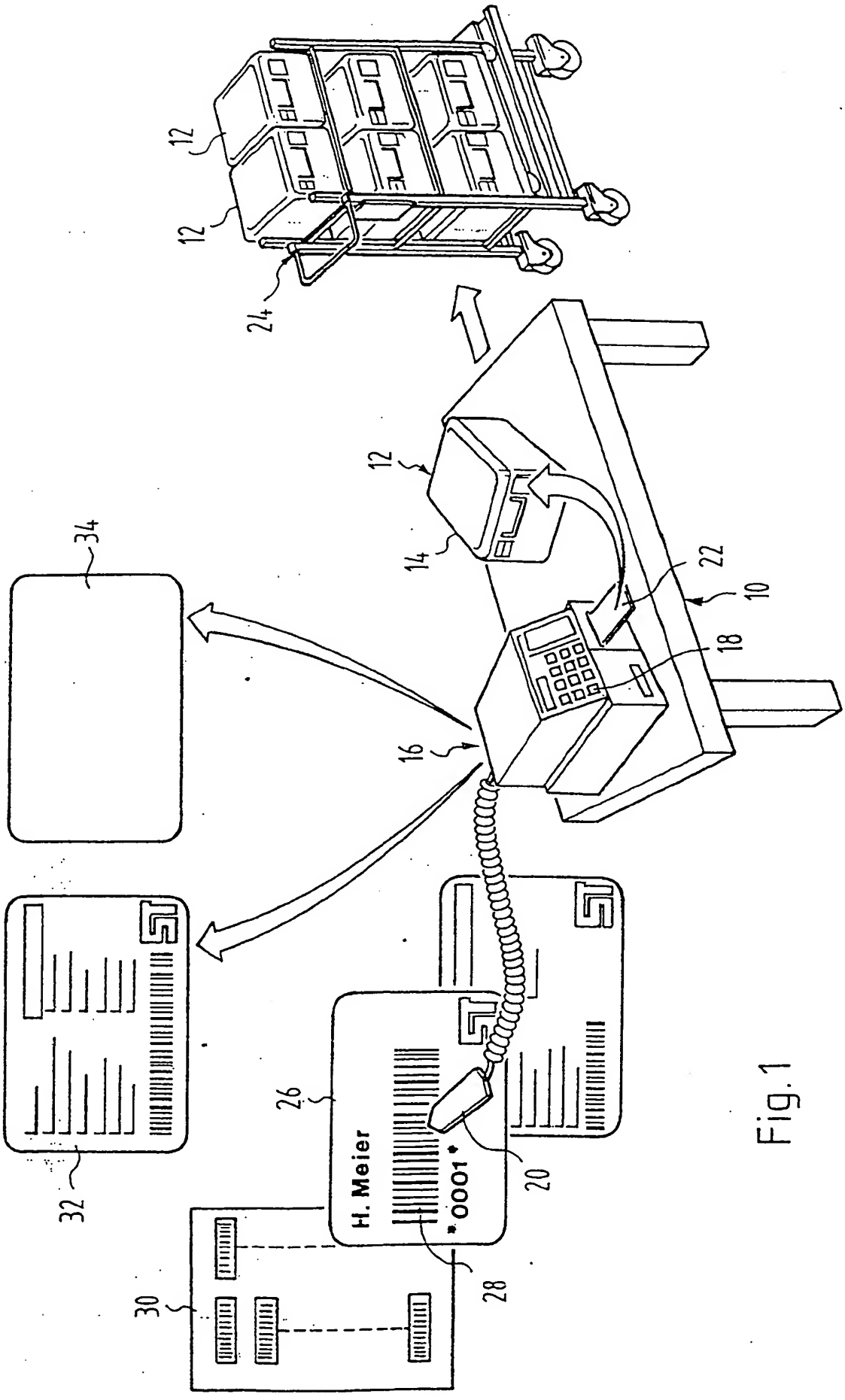
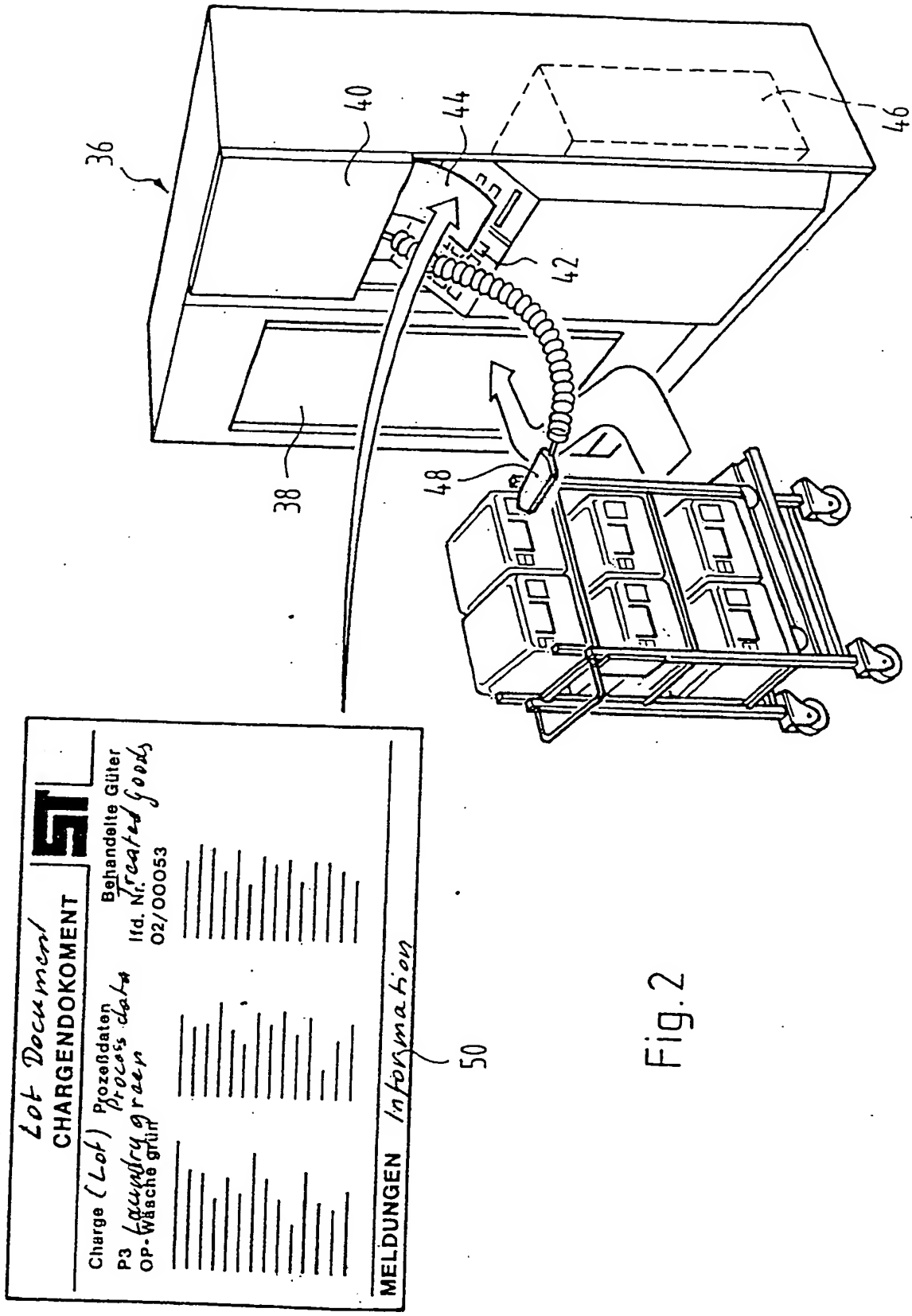


Fig.1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Behandelte Güter
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Fig. 2

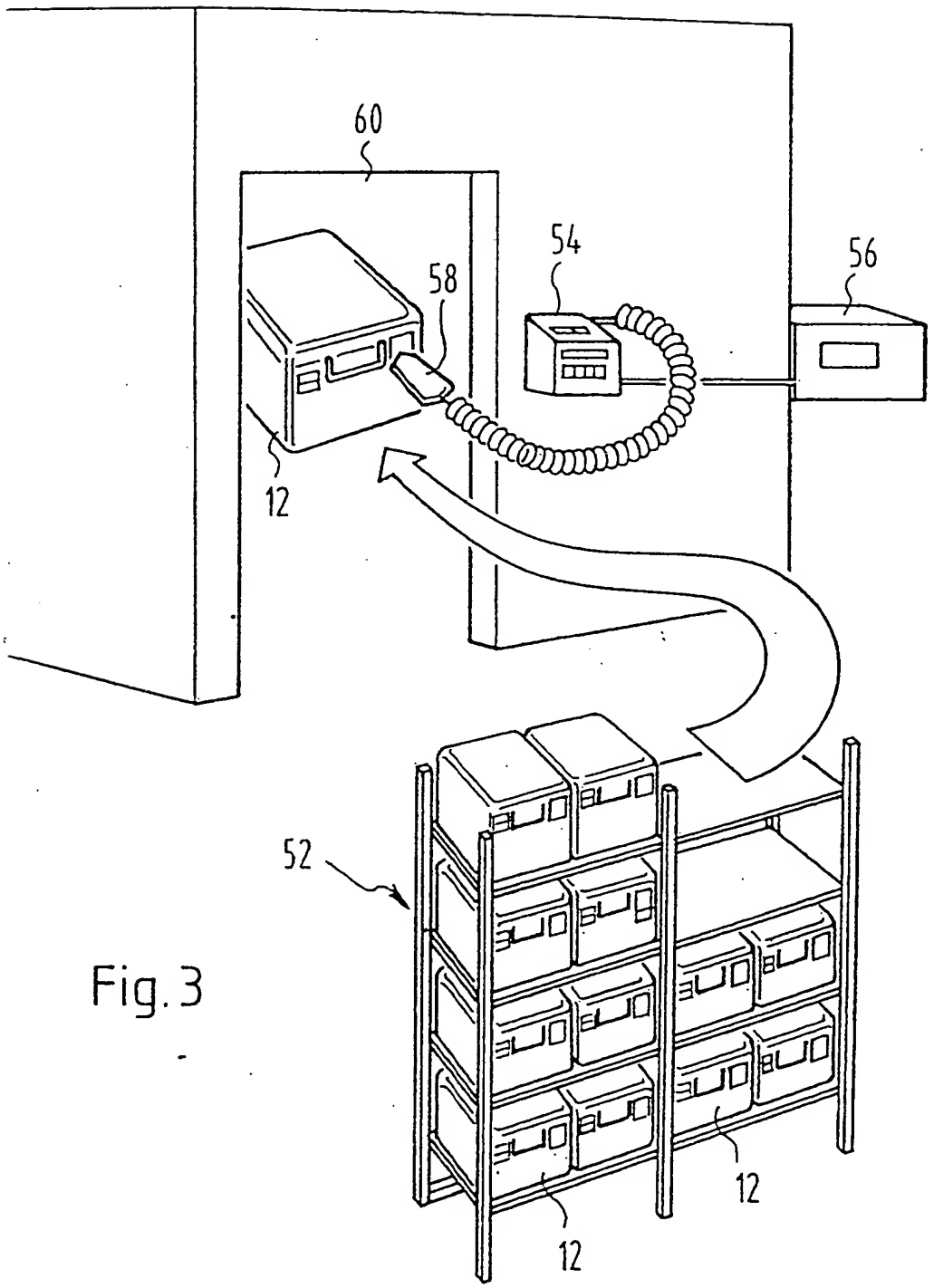

Fig. 3

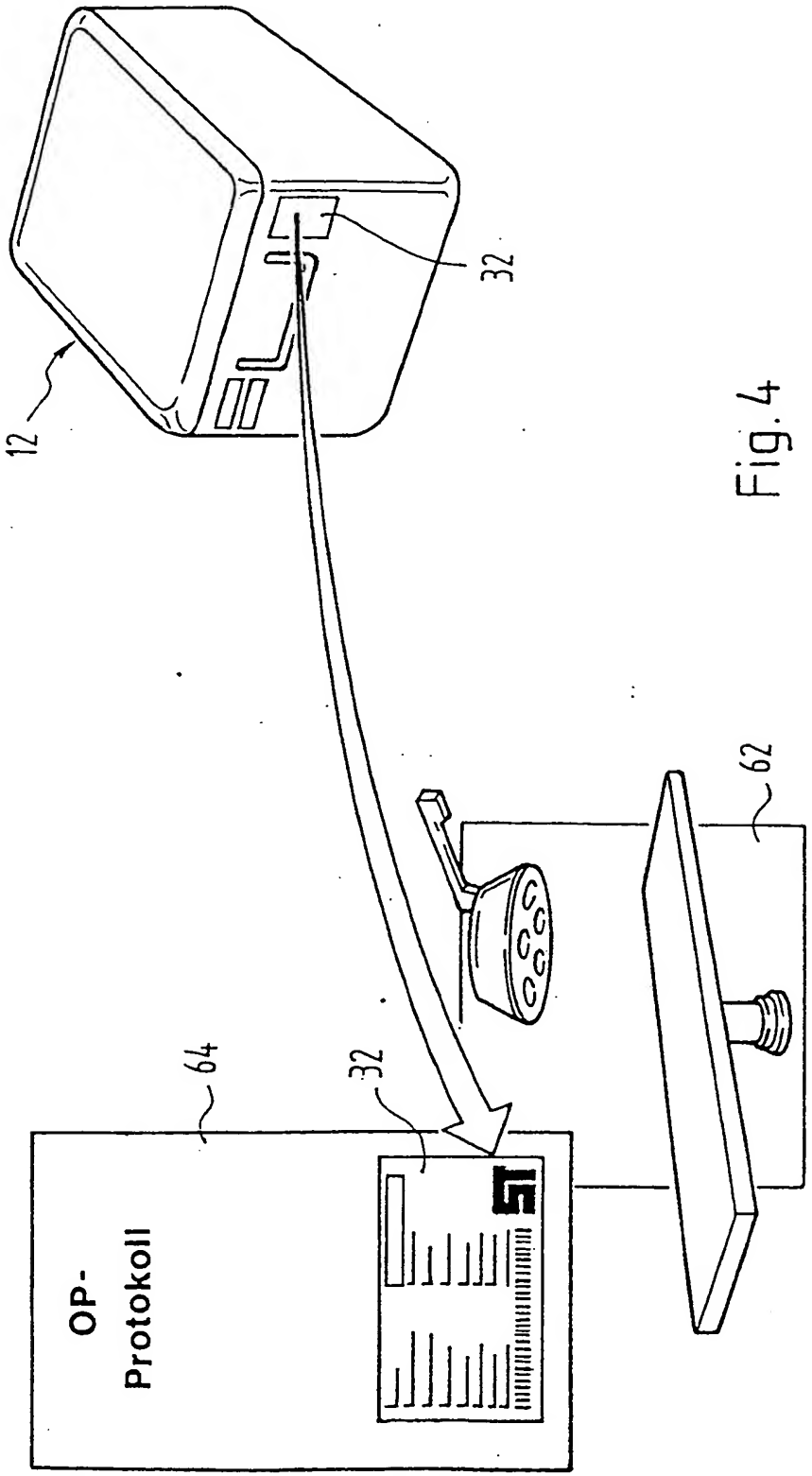

Fig. 4

European Patent Office

Name of the Application

European Research Report

EP 94 10 9105

APPLICABLE DOCUMENTS			
Category	Identification of the document, and, if so required, identification of the relevant sections	Concerning claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 5)
A	DE-A-39 17 876 (AESCULAP) * the entire document * - - - -	1, 12	B65B55/02 A61L2/26 A61B19/00
A	GB-A-2 212 310 (STEP BY STEP CONSULTANTS - - - -		G06K7/10 G06F15/24
			RESEARCHED SUBJECT AREAS (Int. Cl. 5)
			B65B A61L A61B G06K G06F
The presented research report was issued for all patent claims			

Research Location	Finishing Date of the Research	Researcher
Den Haag	September 7, 1994	Hegberg, A

CATEGORY OF THE NAMED DOCUMENTS

X: of special importance by itself
Y: of special importance in combination with another publication of the same category
A: technical background
O: non written publication
P: itermediate literature

T: theories and basics that apply to the invention

E: older patent document, which was, however, published only at or after the application date
D: document that is stated in the application
L: document that is mentioned due to different reasons

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&: member of the same patent family, correlating document